AVIOQ® HTLV-I/II

Microelisa System

For the qualitative detection of antibodies to Human T-Lymphotropic Virus Type I (HTLV-I) and/or Human T-Lymphotropic Virus Type II (HTLV-II) in human serum or plasma. It is intended as a screen for donated organs and blood to prevent transmission of HTLV-I and HTLV-II to recipients of cellular blood components and as an aid in clinical diagnosis of HTLV-I or HTLV-II infection and related diseases.

100% sensitivity and 99.95% specificity*

The performance characteristics of the Avioq HTLV-I/II Microelisa System combined with the simplicity and efficiency of the test format are an unbeatable combination.
The 8-well strip format and only 20µl serum or plasma sample input make this test ideal for automation.

*See package insert for 95% Confidence Intervals

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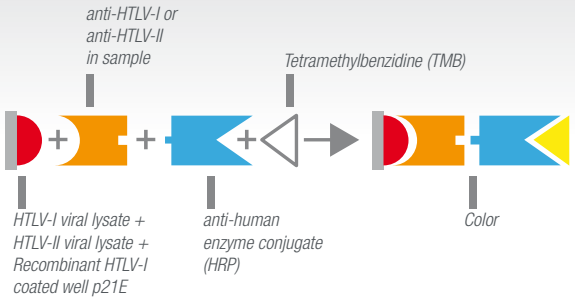
Principle



Avioq HTLV-I/II Microelisa System is an enzyme-linked immunosorbent assay (ELISA) in which the solid phase (microwells) are coated with purified HTLV-I and HTLV-II viral lysate, and a HTLV-I recombinant p21 E antigen. Upon addition of a diluted test specimen containing antibodies to either HTLV-I or HTLV-II, complexes are formed by the interaction of the antibodies in the sample and the solid phase antigens. Following incubation and a wash to remove unbound material, the wells are incubated with the enzyme conjugate, washed again, incubated with Tetramethylbenzidine substrate, and read after the addition of the stop solution.

Features:

- 99.95% specificity in random donor population seen in clinical trials (95% confidence interval of 99.89% to 99.98%)
  Result: Reduced costs for confirmatory testing
- Fast, convenient, procedure: Total incubation time only 2 hours, 30 minutes
  Result: Practical 60/60/30-minute format adapts to laboratory workflow with rapid throughput to results
- Direct dilution into microplate wells
  Result: Eliminates need for time-consuming external dilution step and cost of dilution tubes
- Economical and versatile 8-well strip plate format
  Result: Adaptable to automation and your testing volumes
- Convenient microelisa procedure
  Result: Same day results
- High correlation between initial and repeat results
  Result: Reduces unnecessary repeat testing

Reactivity with Supplemental Test HTLV-I, HTLV-II and HTLV-I/II Antibody Positive Specimens

Group	Supplemental Test Result	No. Tested	No. Repeatedly Reactive
Adult T-Cell Leukemia	HTLV-I	47	47
Tropical Spastic Paraparesis	HTLV-I	43	43
Nasopharyngeal Lymphoma	HTLV-I	1	1
Intravenous Drug Abusers	HTLV-I HTLV-II	5 95	5 95
Total		**191**	**191 (100%)**

Positives from Low Risk Donor Populations

Group	Supplemental Test Result	No. Tested	No. Repeatedly Reactive
Blood Donors	HTLV-I HTLV-II HTLV-I/II	146 138 16	146 138 16
Total		**300**	**300 (100%)**

Reactivity in Normal Donor Population

Sample Type	Total Tested	Initially Reactive	Repeatedly Reactive	Positive by Supplemental Tests
Serum	5069	2 (0.04%)	2 (0.04%)	0
Plasma	5067	3 (0.06%)	3 (0.06%)	0

AVIOQ HTLV-I/II Microelisa System

Description	Product No.	Packaging
Avioq HTLV-I/II	500192	192 Tests
Avioq HTLV-I/II	500576	576 Tests
Avioq HTLV-I/II	509600	9600 Tests
Wash Buffer Concentrate	559879	1 Bottle
Wash Buffer Concentrate	559880	4 Bottles

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US License No. 1856
CE 0086

Avioq HTLV-I/II Brochure 001 Rev0

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